

**INTERVIEW SUMMARY**

In response to the Interview Summary mailed October 5, 2005, Applicants note that a telephone call was made to the Examiner on September 27, 2005, request clarification of the Restriction Requirement relating to the election of species for item 'c' (see bottom of page 7 to middle of page 8). Specifically, the election of species for item 'c' omitted a species listing for item 'ii.' The Examiner stated that the species listing for item 'ii' on page 8 would be the same species listing as provided on page 5 of the Restriction Requirement under item 'iii.' The Examiner also stated that written confirmation of this change to the Restriction Requirement will be provided in an Interview Summary.

Accordingly, in order to complete Applicants' record, Applicants note that the Restriction Requirement includes the election of species as indicated on page 3 of the Interview Summary.

**OBJECTION TO SUPPLEMENTAL PRELIMINARY AMENDMENT**

In response to the objection by the Examiner to the Supplemental Preliminary Amendment filed June 28, 2002, because the Amendment did not include the required statement that the sequence listing information is identical, Applicants note that a Statement that the Content of the Paper and Computer Readable Copies are the Same was filed with the Sequence Listing on June 28, 2002, along with the Supplemental Preliminary Amendment. However, for the convenience of the Examiner, Applicants are hereby providing a copy of the filed Statement and a copy of the filing receipt stamped

by the U.S. Patent and Trademark Office acknowledging receipt of the above-mentioned papers.

## **RESTRICTION REQUIREMENT**

Restriction to one of the following inventions is required under 35 U.S.C. §§121 and 372:

- I. Claims 1-18, drawn to a method for analyzing an interaction between a protein and a molecule.
- II. Claims 19-23, drawn to a labeling agent for a protein.
- III. Claims 24-30, drawn to an immobilized protein and a protein chip.
- IV. Claim 31, drawn to an apparatus for producing a protein chip.
- V. Claim 32, drawn to an apparatus for simultaneous analyses of multiple test samples.
- VI. Claims 33-37, drawn to a method for identifying a molecule which interacts with a protein or a protein that interacts with a molecule.
- VII. Claim 38, drawn to a molecule having interaction with a protein.
- VIII. Claim 38, drawn to a protein having interaction with a molecule.
- IX. Claims 30-40, drawn to a C-terminus labeled protein.

The restriction asserts that the inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features because the technical feature linking Groups I-IX appears to be a C-terminus labeled protein that is capable of interacting with a target molecule, which is shown by Persechini (WO 98/48278). The

restriction asserts that the technical feature linking the inventions of Groups I-IX does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

## **REQUIREMENT FOR ELECTION OF SPECIES**

Furthermore, the requirement states that the application contains claims directed to more than one species of the generic invention. The requirement has required election of a species should Groups I, II, or III be elected, in the following manner.

(a) In the event that Group I is elected, the following species election (for i, ii, iii, and iv) must also be made:

- i. one type of target molecule (claims 1 and 3-18 are generic; claim 2 corresponds to this species), elect one of the following:
  - (1) Protein
  - (2) Nucleic acid
  - (3) Sugar chain
  - (4) Low molecular [weight] compound
- ii. one type of chemical skeleton (claims 1-5 and 7-18 are generic; claim 6 corresponds to this species), elect one of the following:
  - (1) Puromycin
  - (2) 3'-N-aminoacylpuromycin aminonucleoside
  - (3) 3'-N-aminoacyladenosine aminonucleoside
- iii. one combination of polypeptide and molecule (claims 1-10 and 12-

18 are generic; claim 11 corresponds to this species), elect one of the following:

- (1) Biotin binding protein/biotin
- (2) Maltose binding protein/maltose
- (3) G protein/guanine nucleotide
- (4) Polyhistidine peptide/metal ion
- (5) Glutathione-S-transferase/glutathione
- (6) DNA binding protein/DNA
- (7) Antibody/antigen molecule
- (8) Calmodulin/calmodulin binding peptide
- (9) Adenosine triphosphate binding protein/ATP
- (10) Estradiol receptor protein/estradiol

iv. one method of measuring signal change (claims 1-11, 14, and 16 are generic; claims 12-13, 15, and 17-18 correspond to this species), elect one of the following:

- (1) Surface plasmon resonance method
- (2) Evanescent field imaging method
- (3) Fluorescence imaging analysis method
- (4) Enzyme-linked immunoabsorbent assay
- (5) Fluorescence depolarization
- (6) Fluorescence correlation spectroscopy

(b) In the event Group II is elected, the following species election (for i and ii) must be also be made:

- i. one type of labeling moiety molecule (claims 19-21 are generic; claim 22 corresponds to this species), elect one of the following:

- (1) Biotin
- (2) Maltose
- (3) Guanine nucleotide
- (4) Metal ion
- (5) Glutathione
- (6) Protein binding DNA
- (7) Antigen molecule
- (8) Calmodulin binding peptide
- (9) ATP
- (10) Estradiol

- ii. one acceptor moiety chemical skeleton (claims 19-22 are generic; claim 23 corresponds to this species), elect one of the following:

- (1) Puromycin
- (2) 3'-N-aminoacylpuromycin aminonucleoside
- (3) 3'-N-aminoacyladenosine aminonucleoside

(c) In the event Group III is elected, the following species election (for i and ii) must also be made:

- i. one acceptor moiety chemical skeleton (claims 24-27 and 29-30 are generic; claim 28 is subject to species election), elect one of the following:

- (1) Puromycin

- (2) 3'-N-aminoacylpuromycin aminonucleoside
- (3) 3'-N-aminoacyladenosine aminonucleoside
- ii. one combination of molecule constituting the labeling moiety and molecule having specific binding ability (claims 24-28 and 30 are generic; claim 29 is subject to species election), elect one of the following:
  - (1) Biotin binding protein/biotin
  - (2) Maltose binding protein/maltose
  - (3) G protein/guanine nucleotide
  - (4) Polyhistidine peptide/metal ion
  - (5) Glutathione-S-transferase/glutathione
  - (6) DNA binding protein/DNA
  - (7) Antibody/antigen molecule
  - (8) Calmodulin/calmodulin binding peptide
  - (9) Adenosine triphosphate binding protein/ATP
  - (10) Estradiol receptor protein/estradiol.

Based on this grouping of species, Applicants are required to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The requirement states that, currently, no the claims contain more than one species of generic invention.

The requirement also states that upon allowance of generic claim, Applicants will be entitled to consideration of claims to additional species which are written in

dependent form or otherwise include all the limitations of an allowed claims as provided by 37 C.F.R. 1.141.

## **ELECTION**

In response to the requirement for restriction, Applicants elect the invention of Group I (claims 1-18), with traverse. With respect to the election of species requirement, Applicants elect the species of protein for “one type of target molecule,” puromycin for “one type of chemical skeleton,” biotin binding protein/biotin for “one combination of polypeptide and molecule,” and fluorescence imaging analysis method for “one method of measuring signal change”. Applicants note that at least claims 1-18 are generic, and at least claims 1-18 are readable on the elected species.

For the reasons set forth below, Applicants submit that the restriction requirement is improper, and should be withdrawn, whereby an action on the merits of all of the pending claims is warranted.

## **TRAVERSE**

Notwithstanding the election of the claims of Group I in order to be responsive to the requirement for restriction, Applicants respectfully traverse the requirement.

The Examiner is reminded that in determining unity of invention, the criteria set forth in 37 C.F.R. §1.475 must be considered. Specifically, §1.475(a) sets forth the definition of the requirement for unity of invention, and the unity of invention that must be satisfied, where a group of inventions is claimed, in order to have the right to include multiple inventions in a single application. In particular, §1.475(a) states that a national

stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. In this regard, it is stated that:

Where a group of inventions is claimed in an application, the requirement for unity of invention shall be fulfilled only when there is technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression Aspecial technical features@ shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole makes over the prior art.

Further, §1.475(b) defines several combinations of different categories of claims which always fulfill the unity of invention requirements of §1.475(a) where the same or corresponding special technical features is claimed. Thus, the requirement for unity of invention is fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. In the instant situation, the claimed method for analyzing an interaction between a protein and a molecule of Group I can be considered to be analogous to claims directed to the method for identifying a molecule that interacts with a protein or a protein that interacts with a molecule of Group VI, as well as a labeling agent for a protein of Group II, the immobilized protein and protein chip of Group III, the apparatus for producing a protein chip of Group IV, the apparatus for simultaneous analysis of multiple test samples of Group V, and the molecule or protein of Groups VII, VIII, and IX.

Thus, the presently pending claims have unity of invention, whereby the instant restriction requirement is improper, and should be withdrawn.

Still further, the requirement asserts that the inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because under



PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The requirement asserts that the claims lack a corresponding special technical feature because the common technical feature is a C-terminus labeled protein is known and is, therefore, not a contribution over the art (see Persechini (WO 98/48278)). However, the requirement does not indicate how the claims are considered anticipated or obvious over Persechini. The Restriction Requirement fails to bear the burden of proving unpatentability under U.S. Patent law. The Restriction Requirement fails to bear the burden of proving unpatentability, and accordingly, the assertions contained therein are without appropriate basis, and the restriction should be withdrawn.

In view of the foregoing, it is respectfully requested that the Examiner seriously reconsider the requirement for restriction, and withdraw the same to give an examination on the merits on all of the claims pending in this application. In any event, the claims should be rejoined upon allowance of the elected claims.

### **CONCLUSION**

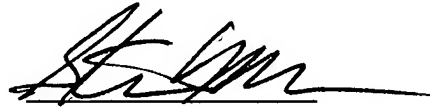
For the reasons discussed above, it is respectfully submitted that the requirement for restriction is improper because unity of invention is present, and the requirement should be withdrawn.

Withdrawal of the requirement restriction with examination of all pending claims is respectfully requested.

Favorable consideration with early allowance of the application is most earnestly requested.

Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,  
Hiroshi YANAGAWA et al.

A handwritten signature in black ink, appearing to read 'H. Bernstein', with a horizontal line drawn underneath it.

Bruce H. Bernstein  
Reg. No. 29,027

October 19, 2005  
GREENBLUM & BERNSTEIN, P.L.C.  
1950 Roland Clarke Place  
Reston, VA 20191  
(703) 716-1191

**Stephen M. Roylance**  
**Reg. No. 31,296**